(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative M+C plans, Medigap options, original Medicare and must receive HCFA approval.

(3) To the general public at least 60 days before the termination effective date by publishing an HCFA-approved notice in one or more newspapers of general circulation in each community or county located in the M+C organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by HCFA and is at least 90 days after the date HCFA receives the M+C organization's notice of intent to terminate.

(d) *HCFA's liability.* HCFA's liability for payment to the M+C organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* HCFA does not enter into an agreement with an organization that has terminated its contract within the preceding 5 years unless there are circumstances that warrant special consideration, as determined by HCFA.

§ 422.514 Minimum enrollment requirements.

(a) *Basic rule.* Except as provided in paragraph (b) of this section, HCFA does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an M+C organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* (1) For a contract applicant or M+C organization that does not meet the applicable requirement of paragraph (a) of this section at application for an M+C contract or during the first 3 years of the contract, HCFA may waive the minimum enrollment requirement as provided for below. To receive a waiver, a contract applicant or M+C organization must demonstrate to HCFA's satisfaction that it is capable of administering and managing an M+C contract and is able to manage the level of risk required under the contract. Factors that HCFA takes into consideration in making this evaluation include the extent to which—

(i) The contract applicant or M+C organization's management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section, or

(ii) The contract applicant or M+C organization has the financial ability to bear financial risk under an M+C contract. In determining whether an organization is capable of bearing risk, HCFA considers factors such as the organization's management experience as described in paragraph (b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to HCFA; and

(iii) The contract applicant or M+C organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(2) If an M+C organization fails to meet the enrollment requirement in the first year, HCFA may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an M+C contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an M+C organization fails to meet the enrollment requirement in the second year, HCFA may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. HCFA may elect not to renew its contract with an M+C organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.516 Reporting requirements.

(a) *Required information.* Each M+C organization must have an effective procedure to develop, compile, evaluate, and report to HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the M+C organization has a fiscally sound operation.

(6) Other matters that HCFA may require.

(b) *Significant business transactions.* Each M+C organization must report to HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in §422.500) between the M+C organization and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the M+C organization and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the M+C organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the M+C organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the M+C organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an M+C organization showing good cause, HCFA may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an M+C organization in its offerings, the M+C organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The M+C organization must furnish the information to the employer or the employer's designee, or to the